

## **Cover Page:**

**Study title:** “Effect of Chemotherapy and Tumor Clearance in Hepatic Resections for Colorectal Liver Metastases. A single-centre Cohort Study”.

**Date:** October 1st, 2021.

**NCT number:** not available.

## Study Protocol:

**Project title:** Effect of Chemotherapy and Tumor Clearance in Hepatic Resections for Colorectal Liver Metastases. A single-centre Cohort Study.

**Project summary:** Retrospective analysis of a prospectively collected database of 170 patients between 2004 and 2020, trying to determine rates and patterns of recurrence following liver resections for CRLM at The Queen Elizabeth Hospital (Adelaide, Australia). We expect to characterise clinical, pathological and treatment-related factors that could function as predictors of recurrence or survival, particularly neoadjuvant chemotherapy and tumour clearance.

### Project description:

**Rationale:** Colorectal cancer is the third most prevalent cancer and accounts for the second leading cause of cancer-related deaths. Up to 50% of CRC patients develop synchronous (10-20%) or metachronous liver deposits (20-30%). Hepatic resection is the gold standard and only curative treatment for colorectal liver metastases. While excision significantly improves survival outcomes, more than 50% of patients experience recurrence after primary hepatic resection and generally, within the first 24 months after surgery.

**Objectives:** To determine rates and patterns of recurrence following liver resections for CRLM at The Queen Elizabeth Hospital (Adelaide, Australia), and concurrently, characterise clinical, pathological and treatment-related factors that could function as predictors of recurrence or survival, particularly neoadjuvant chemotherapy and tumour clearance

**Methodology:** Retrospective analysis of a prospectively collected database of 170 patients between 2004 and 2020, who underwent liver resections for CRLM at The Queen Elizabeth Hospital.

**Data management and analysis:** Prospectively generated liver database that collates epidemiological, clinical and pathological data regarding the primary CRC and the CRLM. In addition, associated laboratory results, operative protocols, pathology reports and patient follow up/outcomes are also reported. Variables will be documented from the date of CRC diagnosis until either a patient's death, loss of follow-up or the end of the study period.

The software "R" version 3.4.1 (The R Foundation) will be used for the statistical analysis. Chi-square test, Fisher's exact test, Student's test and the Wilcoxon test are considered to establish association between recurrences and the proposed predictive variables in univariate analysis.

**Ethical considerations:** This database is approved for research use by the TQEH Human Research Ethics Committee and all data have been managed appropriately under the Australian code for the Responsible Conduct of Research

**Gender issues:** None

**References:**

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- 3) Adam R, de Gramont A, Figueras J, Kokudo N, Kunstlinger F, Loyer E, et al. Managing synchronous liver metastases from colorectal cancer: A multidisciplinary international consensus. *Cancer Treat Rev* [Internet]. 2015 Nov 1 [cited 2019 Jun 18];41(9):729–41. Available from: <https://www.sciencedirect.com/science/article/pii/S0305737215001280>
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